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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,894	12/21/2001	William Canfield	217139US77	5451

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EXAMINER

PATTERSON, CHARLES L JR

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 10/21/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/023,894

Applicant(s)

CANFIELD ET AL.

Examiner

Charles L. Patterson, Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/21/02, 3/24/03, 7/23/03, 6/25/03.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) 11-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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Applicant's election with traverse of Group I, claims 1-10 in Paper No. 10 is acknowledged. The traversal is on the ground(s) that the examiner has not shown that a burden exists in searching the entire application. This is not found persuasive because Groups 1-2 are drawn to two apparently different processes for producing a lysosomal hydrolase, one involving culturing cells in the presence of *Pseudomonas* exotoxin A and the other introducing the polynucleotide into a furin deficient cell. Groups 3-5 involve producing phosphodiesterase α -GlcNAcase, a different enzyme from that of groups 1-2. The three groups involve culturing the cell containing the gene in two completely different substances or expressing the enzyme in a furin deficient cell. Since the groups are drawn to methods of producing two different enzymes by completely different processes, it is maintained that it would be a burden upon the examiner to search all of the groups. Also involved in examination is utility, written description and enablement, which may involve completely different things for each of the five groups.

The requirement is still deemed proper and is therefore made FINAL.

Claims 11-44 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

Several references are crossed out in the enclosed PTO-1449 as they are not present in the file or in the storage location for large IDSs.

Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 1 is incorrect in the recitation of "N-acteylglucosamine" in lines 2 and 9, which should be "N-acetylglucosamine".

Claim 2 is confusing in the recitation of "or" on line 3. Why is this "or" in the middle of a long series of items? The claim is also confusing in the recitation of "Arylsulfatase A Cerebroside" and "Ganglioside" in line 8. These substances apparently are not hydrolases as they do not end in "ase".

Claim 3 is incorrect in the recitation of "N-acteylglucosamine" in line 2, which should be "N-acetylglucosamine".

Claims 4 and 5 are indefinite in the recitation of "said phosphodiester α -GlcNAcase, which has no antecedent basis.

Claim 4 is confusing and indefinite in the recitation of "an amino acid 56 to 515 of SEQ ID NO:18". It is not known what is meant by this phrase. Is the recitation perhaps meant to indicate amino acids 56-515 of SEQ ID NO:18?

Claim 6 is indefinite in the recitation of "said glycoprotein", which has no antecedent basis.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at

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the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The specification apparently does not recite " α -galactosidase A" and " β -galactosidase" as in the instant claim. The recitation in the paragraph spanning pages 16-17 is " β -galactosidase A" and "-galactosidase". Apparently it is not recited elsewhere in the specification.

Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention and in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is a combination written description and enablement rejection.

The examiner can find no teaching in the specification teaching that lysosomal hydrolases having an oligosaccharide modified as in claim 1 can be produced by contacting a mammalian cell culture expressing such an enzyme with a mutagenic agent in the presence of *Pseudomonas* exotoxin A. Apparently, the only mention of *Pseudomonas* in the specification is on page 15, lines 1, 3, 5 and 6, and these recitations do not refer to a "*Pseudomonas* exotoxin A" but rather to a *Pseudomonas* exodotoxin A". These are two different substances. There is no teaching in the specification that if cells are selected that are resistant to either "*Pseudomonas* exotoxin A" or "*Pseudomonas* exodotoxin A", the lysosomal hydrolase of claim 1 would be produced. Therefore, the specification does not enable one of ordinary skill in the art to make and/or use the claimed invention and furthermore this ordinary artisan

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reading the instant specification would not believe that applicant had possession of the claimed invention at the time of filing.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 703-308-1834. The examiner can normally be reached on Monday - Friday, 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone number is 703-308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Charles L. Patterson, Jr.
Primary Examiner
Art Unit 1652

Patterson
October 20, 2003\